PATENT COOPERATION TREATY

REC'D 23 NOV 2004
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From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* 19 NOV 2004

Applicant's or agent's file reference
KKSS:205407577

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/AU2004/001367	7 October 2004	7 October 2003

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. [7] C12N 5/00, B01D 57/02

Applicant
UNIVERSITY OF NEWCASTLE et al

1. This opinion contains indications relating to the following items:

- [X] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [X] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/AU2004/001367

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing
      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format
      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in the international application as filed.
      ☐ filed together with the international application in computer readable form.
      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-26	YES
	Claims		NO
Inventive step (IS)	Claims	1-26	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-26	YES
	Claims		NO

2. Citations and explanations:

The invention resides in a method of using an electrical potential to drive sperm cell isolation/enrichment/separation. The electrical potential is used to separate sperm cell sub-populations across a suitable ion-permeable electrophoresis membrane.

The following documents (D) from the ISR are referred to in this communication:

D1: WO 2002/024314 (The Texas A & M University System et al.) 28 March 2002.

D2: WO 2002/093168 (Gradipore Ltd) 21 November 2002.

D3: DE 10149875 (Alpha Technology Gesellschaft für Angewandte Biotechnologie mbH i.Ins.) 3 July 2003.

D1 describes the membrane-based electrophoresis apparatus used in the method of the present application. D1 suggests that the apparatus disclosed is suitable for electrophoresis of biomolecules including "protein, peptides, glycoproteins, nucleic acid molecules, recombinant molecules, metabolites, neutraceuticals, pharmaceuticals, microorganisms including viruses, bacteria, fungi and yeasts, and prions" (P.4 lines 28-30). Nowhere in this citation is it suggested that sperm sub-populations have different charge characteristics, or that this property can be exploited to obtain sperm sub-populations using membrane-based electrophoresis.

D2 describes a membrane-based electrophoresis method to detect the presence of prions in biological samples, including sperm.

D3 describes a two chamber electrophoresis apparatus used to separate/extract biopolymers (eg DNA, RNA, PNA, or proteins). The apparatus can be used to extract analytes from medical samples including sperm.

Insomuch as none of the citations disclose membrane-based electrophoresis as a method to separate sperm cell sub-populations the invention appears to be novel and inventive.